REMARKS

The amendment submitted in this case on February 24, 2003, in reply to the final Office Action mailed on August 23, 2002, was not entered (see Advisory Action mailed April 25, 2003). Applicants respectfully request entry of the amendment set forth above, as well as reconsideration of the pending claims. The rejections made in the final Office Action are addressed as follows.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 14-16, 19, 29, and 30 were rejected under 35 U.S.C. § 112, second paragraph on several grounds, which are addressed as follows.

Claims 14-16 were rejected for reciting method steps in the passive voice. This rejection has been overcome by the present amendment to claims 14-16, in which these claims have been amended to recite steps in a positive manner, as was suggested in the final Office Action.

Claim 19 was rejected as being indefinite for depending from claim 1 and reciting the phrase "further consisting essentially of an additional Helicobacter antigen." Applicant respectfully disagrees with this rejection but, in the interest of expediting prosecution, has amended claim 19 so that it no longer depends from claim 1.

Claims 29 and 30 were rejected on the basis that it is not clear whether the additional Helicobacter antigen (claim 29) or adjuvant (claim 30) impact the appearance of the molecular weight of the claimed protein when fractionated by SDS PAGE. Claim 30 has been canceled. With respect to claim 29, this rejection has been met by the present amendment to this claim, by which the claim now clearly states that the claimed composition includes two separate components: (i) a polypeptide that appears to be on the order of 54 kDa, and (ii) an additional

Helicobacter polypeptide antigen. Applicants thus respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 101

Claim 17 was rejected under § 101 on the basis that the claimed protein may exist in nature in the form that is claimed. This rejection has been met by the present amendment to claim 17, which now specifies that the protein is isolated. Applicant thus respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102

The claims were rejected under 35 U.S.C. §§ 102(b) and (e) over several references[1] that describe fractionation of Helicobacter protein preparations on gels, and detection of bands on these gels that have sizes that are similar to the sizes of the proteins now claimed. Some of these references, as well as an additional reference,[2] were also cited for describing antibodies that recognize proteins having these or similar sizes. None of the cited references anticipate the present claims.

To address this rejection, applicant would first like to discuss the meaning of the term "consisting essentially of" in the present claims. As is stated in M.P.E.P. § 2111.03, this phrase "limits the scope of the claim to the specified materials or steps 'and those that do not materially

[1] Husson et al., Infection and Immunity 61:2694-2697, 1993
Calenoff, U.S. Patent No. 5,567,594
Bölin et al., Journal of Clinical Microbiology 33:381-384, 1995
Doig et al., Infection and Immunity 62:4526-4533, 1994
Alemohammad, U.S. Patent No. 5,262,156
Pronovost et al., U.S. Patent No. 5,846,751
Pronovost et al., U.S. Patent No. 5,814,455
[2] Ruiz et al., WO 94/06474

affect the basic and novel characteristic(s)' of the claimed invention" (citations omitted; emphasis in original). To determine what could be encompassed in claims that include this term, it only makes sense to look at the specification, which describes the basic and novel characteristics of the invention.

As is made clear throughout the specification, the focus of the invention is Helicobacter proteins of about 54, 50, 32-35, or 30 kDa, compositions including these proteins, and methods employing these proteins. Indeed, the specification provides extensive details as to how to obtain these proteins, and these methods result in the recovery of the proteins in a highly purified form. Thus, a basic characteristic of the invention is the 54, 50, 32-35, or 30 kDa Helicobacter proteins that are in a highly purified form. Based on this, it is clear that prior art teachings of, e.g., Helicobacter membrane fractions do not anticipate claims specifying compositions that "consist essentially of" the present proteins, because such compositions include material that alter a basic characteristic of the invention: the 54, 50, 32-35, or 30 kDa proteins that have been obtained in a highly purified form.

That is not to say that other proteins cannot be included in the compositions of the invention. As is stated on page 12, line 36 - page 13, line 2 of the specification, "a composition according to the invention may comprise in addition to a protein or a polypeptide according to the invention, at least one other Helicobacter antigen such as the urease apoenzyme, or a subunit, fragment, homologue, mutant or derivative of this urease." Thus, compositions of the invention can include Helicobacter proteins other than the 54, 50, 32-35, or 30 kDa protein, provided that the protein of the invention that is present in such compositions has been obtained in a highly purified form, prior to addition of the other proteins. As another example, page 13, line 3 - page 14, line 7 describes adjuvants that can be included in compositions of the invention. Including

adjuvants in the compositions does not alter the basic characteristics of the invention, because they are clearly intended to be included with the highly purified proteins of the invention, while components of, e.g., membrane fractions are not.

Claims 1, 19, 20, 29, and 30 were rejected under § 102(b) as being anticipated by Ferrero (Proc. Natl. Acad. Sci. U.S.A. 92:6499-6503, 1995). The Office cites this reference for teaching a composition containing Helicobacter urease and a 54 kDa heat shock protein, as well as a composition containing a 54 kDa heat shock protein and cholera toxin. This rejection can now be withdrawn, because claim 1 has been amended to specify a composition that consists of certain antigens, none of which is 54 kDa; claim 19 is now drawn to a composition that consists of certain antigens, none of which is 54 kDa, and an additional Helicobacter polypeptide antigen; claim 20 is now drawn to a composition that consists of certain antigens, none of which is 54 kDa, and a urease antigen; and claim 30 has been canceled, without prejudice.

Regarding claim 29, applicant notes that Ferrero does not describe a composition that consists essentially of a 54 kDa protein and urease in a form that is acceptable for administration to humans, as is required by this claim. Rather, the passage referred to by the Office as describing such a composition (page 6499, sentence bridging columns 1 and 2) merely notes that urease and a 54 kDa protein have been observed to be associated with one another, not that such proteins were together in a composition, a form acceptable for administration to humans. Applicant thus requests that the rejection over the Ferrero reference be withdrawn.

Applicant further notes that, as is stated above, newly added claim 41 specifies that the protein of this claim is in "substantially purified form," a phrase that was present in the claims as originally filed, and thus which has already been examined in this case. A protein is in a "substantially purified form," according to applicant's definition, if it is "separated from the

medium in which it exists naturally" (page 3, lines 6-10 of the specification). The Office has in the past taken the position that this definition includes lysates, such as those described in the cited references, because such a form is not that which naturally occurs. As is discussed further below, applicants respectfully disagree with this interpretation of their definition.

To fully understand what is meant by applicant's definition, it is helpful to look at the definition in the context of the remainder of the teachings of the specification. As is discussed above, a central focus of the specification is the description of methods for purifying *H. pylori* proteins of 54, 50, 32-35, or 30 kDa, as well as methods for using these proteins in, e.g., diagnostic and immunization methods. Indeed, the invention is based on the identification of these specific proteins and their use in these and other methods. Nowhere does the specification mention the use of lysates for any purpose other than as a source for purifying the specific proteins noted above. Thus, to conclude that applicant would intend to include lysates in their definition would be inconsistent with the teachings of the application as a whole, and thus applicant respectfully submits that those reading the application would clearly see that the phrase "substantially purified form" does not include within its scope lysates, such as those of the cited references. In view of this, applicant respectfully submits that claim 41 is also free of the prior art.

CONCLUSION

The rejections made in the final Office Action mailed on August 23, 2002, as well as the points made in the Advisory Action mailed on April 25, 2003, have been addressed by the Amendments and Remarks provided herein. Applicant thus respectfully requests that the rejections in this case be withdrawn, and that the present claims be allowed to issue. In addition, in the event that any further issues remain in this case, applicants respectfully request that the Examiner contact the undersigned by telephone prior to taking any further actions on the merits. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: August 22, 2003

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